

## Remarks and Response

### Rejections under 35 USC 102

Claims 1 and 2 have been rejected under 35 USC 102(b) as being anticipated by Hutchens. The Applicants respectfully disagree. It is settled law that, under 35 USC § 102, anticipation "requires that each and every element of the claimed invention be disclosed in the prior art." *Akzo N.V. v. U.S. International Trade Commission*, 1 USPQ 2d 1241, 1245 (Fed. Cir. 1986), cert. Denied. 482 U.S. 909 (1987). Specifically, the Examiner states:

"...Hutchens teaches an extract of *Scutellaria laterifolia* (also known as *Scutellaria lateriflora*): "DOSE: Tinture alone, 3-12 drops in water as indicated. As an intrusion [apparent misspelling of infusion], 1 teaspoonful of the cut or powdered herb steeped in 1 cupful of boiling water for ½ hour" ... Hutchens does not expressly teach that the reference extract comprises each of the claim-designated flavonoids having the claim-designated percent amount by weight. However, the plant source material and the ingredients used in the making of the plant extracts taught by Hutchens are one and the same as instantly disclosed by the Applicant. Thus, the claim-designated flavonoids having the claim-designated percent amounts by weight are considered inherent to the extract of *Scutellaria laterifolia* taught by Hutchens." (Emphasis added).

Additionally, in the section rejecting the pending claims under 35 USC § 103, the Examiner admits that Hutchens does not "teach that instantly claimed process step for separating solid material from the solution after a predetermined period and stirring the solution for a predetermined period." As a matter of law, therefore, Hutchens cannot anticipate the pending claims.

In the above analysis the Applicants believe the Examiner misapplies the inherency doctrine. As directed by the courts, inherency "cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established." *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993); MPEP § 2141.02. The composition and concentrations of flavonoids, as claimed in the instant invention, were not known in the art at the time of the invention. Even, *arguendo*, if the compositions of the instant invention, as claimed, were known in the prior art, "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). The facts in *In re Rijckaert* are analogous to the facts in the present Action. In *In re Rijckaert* the Federal Circuit

reversed a rejection because the Examiner based inherency on what would result due to optimization of conditions (as the Examiner has done in the present Action), not what was necessarily present in the prior art. The Applicants contend that the instant invention provides novel compositions and process for making those compositions that are not, as determined by the dicta of the courts cited above, inherent in the prior art because the compositions and concentrations, as claimed, were not known or inherent in the prior art. Because of the forgoing, the Applicants believe that the rejection based on inherency is traversed and the claims are in position for allowance.

Rejections under 35 USC 102 / 35 USC 103

Claims 1-4 and 6-7 have been further rejected under 35USC 102(b) as anticipated by Hutchens or, in the alternative, under 35 USC 103(a) as obvious over Hutchens in view of Green, et al., Sheu et al., Wang et al., and Charaux et al.

The Applicants respectfully traverse this rejection. The Applicants remind the Examiner that a *prima facie* case of obviousness requires citation to a combination of references that a) disclose each and every aspect of the invention as required by the courts, b) provide motivation in the art to combine those elements to yield the claimed combination, and c) provide a reasonable expectation of success should the claimed invention be carried out. Failure to establish anyone of the three requirements precludes a finding of a *prima facie* case of obviousness and, without more, entitle the Applicants to allowance of the claims in issue. See, *Northern Telecom, Inc. v. Datapoint Corp.* 15 USPQ 2d 1321, 1323 (Fed. Cir. 1990) and MPEP 2141. The Applicants respectfully submit that the Examiner has failed to establish any of these three elements of a *prima facie* case of obviousness. In addressing this rejection the Applicants directs their remarks in view of independent Claims 1 and 3 as Claims 2, 4, 6 and 7 are dependent there from and, therefore, are *per se* non-obvious if the dependent claims from which they depend are found non-obvious. See, MPEP 2143.03.

A proper analysis, in view of 35 USC § 103, demands the references cited by the Examiner be considered as a whole and must suggest the desirability and, thereby, the obviousness of making the combination. *Hodash v. Block Drug Co., Inc.* 786 F.2d 1336, 1143, n. 5, 229 USPQ 182, 187, n.5 (Fed. Cir. 1986). Applicants submit that the references cannot be considered collectively until the Examiner points to some motivation to combine said references. This analysis prevents the Examiner from using the instant Specification to reconstruct, in

hindsight, the invention as claimed. The Federal Circuit has articulated the policy behind this analysis:

"To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet, et al.* 149 F.3d 1350, 47 USPQ 2d 1453 (Fed. Cir. 1998).

None of the art cited by the Examiner suggests the desirability of making the combination of elements that would recapitulate the claimed embodiment on the present invention. Specifically, the Patent Office states:

"...The referenced composition [as taught by Hutchens] appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition for the following reasons: Although Hutchens does not expressly teach that the referenced extract has a content of flavonoids calculated as the sum of the claim-designated flavonoids ... the Office deems that the extract taught by Hutchens comprises the instantly claimed ingredients ..."

and,

"Although Hutchens does not expressly teach that instantly claimed process step for separating solid material from the solution after a predetermined period and stirring the solution for a predetermined period, it is generally assumed in the art that the preparation of a plant extract includes the instantly claimed process steps, as evidenced by Green ..."

Furthermore, the Patent Office states:

"In the alternative, even if the claimed composition and method of making thereof are not identical to the teachings of Hutchens ... the claimed process of making thereof would have been obvious to those of ordinary skill in the art within the meaning of USC 103. ... Firstly, Sheu teaches a method for obtaining various flavonoids from the plant material [root] of a *Scutellaria* plant, i.e., baicalin, baicalein, wogonin ... Secondly, Wang teaches a method for obtaining various flavonoids from the plant materials [roots or leaves] ... Thirdly, Charaux teaches a method for the extraction of baicalin in leaves of *Scutellaria* by extracting fresh leaves and acidifying while hot."

It is the Examiner's burden to present "evidence" and this showing must be "clear and particular." *In re Dembiczkak*, 175 F.3d 994, 1000 (Fed. Cir. 1999). As none of the cited references suggest a motivation to combine the cited art the Applicants respectfully submit that the Examiner incorrectly presents bald conclusions in place of reasoned analysis, as required by the Federal Circuit, to combine the cited art.

Importantly, since an Examiner is, under the law, not considered one skilled in the art, the Examiner's opinion as to what one skilled in the art may (or may not) believe is of no moment. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ 2d 1955, 1956 (Fed. Circ. 1993). ("[T]he Examiner's assumptions do not constitute the disclosure of the prior art"). If the Examiner has knowledge of facts relevant to any pending rejections, the Examiner may file an affidavit to make those facts of record in the prosecution. MPEP 2144.03. The Examiner has submitted no such affidavit.

Even if the references cited by the Examiner are improperly combined, these references still fail to teach each and every element of the invention as claimed. As directed by the courts, obviousness "cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established." *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). MPEP § 2141.02. Even in combination, the references cited by the Examiner fail to disclose the compositions and concentrations of flavonoids as claimed in the instant invention. Thus, the Examiner has presented no evidence to show that the composition and concentration of flavonoids, as claimed in the instant invention, were known at the time the invention was made. Therefore, the Examiner's insistence that the invention as claimed is obvious either directly or based on the asserted inherency of the composition of flavonoids as claimed is without basis.

In sum, the Examiner provides only opinion and conclusory statements in support of the pending rejections under 35 USC § 103. These opinions and conclusions may not be considered "evidence" and, in view of the above-cited case law, are inadequate to sustain an obviousness rejection. Accordingly, the Applicants maintain that the Claims are not obvious and should be passed to allowance.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

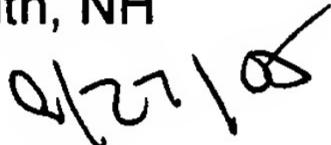
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